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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|-------------------------------|---------------------|------------------|
| 09/126,816 | 07/31/1998 | CHRISTOPH VON EICHEL-STREIBER | PM254992 | 9336 |
| 909 | 7590 | 11/18/2003 | EXAMINER | |
| PILLSBURY WINTHROP, LLP | | | NICKOL, GARY B | |
| P.O. BOX 10500 | | | ART UNIT | PAPER NUMBER |
| MCLEAN, VA 22102 | | | 1642 | |
| DATE MAILED: 11/18/2003 | | | | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|----------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/126,816 | VON EICHEL-STREIBER ET AL. |
| | Examiner | Art Unit |
| | Gary B. Nickol Ph.D. | 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 November 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 30-34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s). 32
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Response to Amendment

The supplementary Amendment filed November 5, 2003 (Paper No. 30) is acknowledged and has been entered.

Claims 1-29 were cancelled.

Claims 30-34 were added and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The objection to the specification under 35 USC 132 made in Paper No. 24, page 3 (Office Action mailed 08/13/2002) is hereby re-instated. Applicants amended the specification to incorporate the sequence of LT as disclosed by Green *et al.* on page 3 of the disclosure. Applicants further filed a declaration (Paper No. 31; November 13, 2003) in support of the amendatory material of SEQ ID NO:6 as consisting of the same material taught in the Green *et al.* reference.

However, upon re-searching and comparing amino acids 1-1700 SEQ ID NO:6 to the sequence disclosed by Green *et al.* it appears that the sequence filed by applicants is not exactly the same material as disclosed by Green *et al.* (see attached sequence listing indicating several mismatches). Hence, it is requested that applicant replace SEQ ID NO:6 with one that is 100%

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identical to the 2364 amino acid sequence disclosed by Green *et al.* Further, the following should be prepared in response this Action:

- 1) File a substitute computer readable form (CRF) copy of the "Sequence Listing"
- 2) File a substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- 3) Include a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).
- 4) File a new affidavit or declaration (executed by the applicant, or a practitioner representing the applicant) stating that the amendatory material consists of the same material incorporated by reference in the referencing application.) See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 112

Claims 30-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 30-34 have been amended to include SEQ ID NO:6 and are considered new matter for the reasons above with regards to the objections of the specification.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
November 14, 2003

